



Protecting the Health of Women: How the FDA Serves Women's Health-Care Needs

Some of the brightest highlights of the FDA's long history are actions to protect the **health of women**. Over the years, the agency has addressed the health issues of the nation's largest population group through means as varied as consumer information, product approvals, research requirements and support for studies.

Examples of these activities include the FDA's first package insert with **information** for consumers, issued in 1971 to explain to women the benefits and risks of oral contraceptives. They include **marketing approvals** for such landmark products as the first over-the-counter pregnancy test kit, and one of the agency's most effective **public health campaigns**, which helped reduce the incidence of toxic shock syndrome from 814 cases and 38 deaths in 1980 to 5 cases and no deaths in 1997.

One of the FDA's most significant recent actions was a rule issued in 2000 that enables the agency to halt studies of new drugs to treat life-threatening diseases if those clinical trials exclude women participants solely because they could become pregnant. The regulation countered the historical tendency to bar women of childbearing

potential from clinical trials because of fear that they might become pregnant and the studied drug might harm the fetus. As a result, in the past, many new drugs were marketed without adequate testing in women.

Other women-oriented FDA priorities in the last decade were focused on preventing the spread of HIV. For example, the FDA requires that HIV drug labels include information on how to prevent the transmission of the disease from mother to infant. In addition, the agency has launched several innovative programs for women:

- After the passage of the **Mammography Quality Standards Act of 1992**, the agency rapidly announced high standards designed to ensure that all mammograms are of the highest quality, and it initiated inspections of the approximately 9,500 mammography facilities in the United States. The program increased the number of facilities that met the image quality standards from 76 percent in 1994 to 98 percent in 1997.
- The FDA is sponsoring a **faith-based mammography initiative**, an outreach program that targets African American and Hispanic women, who have a disproportionately low turnout for mammography screening. In Houston, 150 churches working with the FDA have delivered the

New Products for Women

In 2001, the FDA approved several important products for women, including two drugs for the treatment of metastatic breast cancer and two contraceptive devices that deliver continuous doses of progestin and estrogen to prevent pregnancy. One of the devices, which releases the hormones through the skin into the bloodstream, is the first skin patch approved for birth control.

message "Early Detection Saves Lives" to 110,000 people.

- **"Take Time To Care"** is an award-winning FDA grass-roots campaign that delivers—in 13 languages, and primarily to women over 45 in underserved communities—a brochure with advice on how to take medications properly. With the help of 20,000 drug stores, the media, and civic groups, the message has reached an estimated 26 million people.
- The FDA's **Office of Women's Health**, established in 1994, supports research, outreach, and women's health-associated policy development inside and outside the agency.

For more information, contact the FDA's Office of Women's Health at 301-827-0350 (www.fda.gov/womens) or visit the National Women's Health Information Center at www.4woman.gov.